

# Spinal cord stimulation in painful diabetic peripheral neuropathy

Citation for published version (APA):

Slangen, R. (2018). *Spinal cord stimulation in painful diabetic peripheral neuropathy: clinical- and cost-effectiveness*. [Doctoral Thesis, Maastricht University]. Datawyse / Universitaire Pers Maastricht. <https://doi.org/10.26481/dis.20180221rs>

## Document status and date:

Published: 01/01/2018

## DOI:

[10.26481/dis.20180221rs](https://doi.org/10.26481/dis.20180221rs)

## Document Version:

Publisher's PDF, also known as Version of record

## Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
- The final author version and the galley proof are versions of the publication after peer review.
- The final published version features the final layout of the paper including the volume, issue and page numbers.

[Link to publication](#)

## General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal.

If the publication is distributed under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license above, please follow below link for the End User Agreement:

[www.umlib.nl/taverne-license](http://www.umlib.nl/taverne-license)

## Take down policy

If you believe that this document breaches copyright please contact us at:

[repository@maastrichtuniversity.nl](mailto:repository@maastrichtuniversity.nl)

providing details and we will investigate your claim.

# 11. VALORIZATION



Changes in human behavior and lifestyle have resulted in a dramatic increase of diabetes mellitus (DM) worldwide. In the Netherlands alone, the number of people with type 2 DM is rapidly increasing with an estimated prevalence of 1.2 million people. Up to 50% of the patients with DM develop diabetic peripheral neuropathy (DPN). However, not all patients with diabetes will develop a painful DPN (PDPN). PDPN is associated with high pain scores, and may cause physical and emotional suffering with severe impact on Quality of Life (QoL) and resulting cost-of-illness. This trend is alarming, and it demands policy measures on the part of the government and health care sector and the search for effective and cost-effective treatment modalities for this specific group of people. As the current pharmacological treatment often is only partially effective or unsuccessful due to unacceptable side-effects further research into the pathophysiology of PDPN is necessary. This knowledge can help to improve and develop new treatment modalities for PDPN. Spinal cord stimulation (SCS) is considered a possible last resort treatment modality to treat patients who do not experience sufficient pain relief due to pharmacological treatment.

In this thesis, we have shown that pain coverage of both lower extremities can be achieved with the use of only one Octlead, that it is safe and an effective intervention in pain reduction in PDPN. The favorable results of the pilot study justified performing a larger randomized clinical trial (RCT). In a multi-center randomized clinical trial we have shown that conventional SCS has a short- and long-term treatment effect on pain and Quality of Life (QoL) in PDPN patients and is accompanied with limited side effects. As shown in a recent publication by the departmental research team, 55% of the patients had a treatment success after 5 years and 80% of the patients with PDPN still use their device after 5 years of treatment. Our secondary analysis in the cost-effectiveness study indicated that SCS is likely to become cost-effective within 4 years, but nevertheless, SCS requires a substantial initial investment and follow-up of patients. Furthermore, there is also a group of patients that does not respond well to SCS or experiences a reduction in treatment effect over time. Continuing the search for the underlying pathophysiologic mechanism of PDPN and the underlying mechanism of long-term SCS can optimize SCS in PDPN. In addition, it would be favorable in predicting long-term success in PDPN patients due to SCS. In our study we implemented the Michigan Diabetic Neuropathy Score (MDNS) in the screening of the PDPN patients. However, no differences in MDNS scores in the patients with a negative trial stimulation were observed. It is conceivable that the MDNS is not an adequate predictive tool, as it is a composite measure, and therefore it would be difficult to discriminate between the different factors included in this score. In contrast to our study, a recent publication of the departmental research team, combining the patients of the pilot- and RTC study, showed that the severity of the neuropathy is associated with a higher chance of long-term treatment failure during 5 years follow-up. Not just the search for a SCS outcome predictor, but also the search for

optimal stimulation parameters (frequency, waveform and polarity) is an option, including high frequency (HF) stimulation, burst stimulation and Dorsal Root Ganglion (DRG) stimulation. However, the working mechanisms of HF- and burst stimulation are still a topic of debate and further research is needed to optimize the stimulation settings for PDPN patients, and thereby for all neuropathic pain patients, and should be investigated in a randomized clinical trial. In addition, technology of neurostimulators is developing rapidly, delivering a large set of parameter combinations, and rechargeable batteries are available, but are quite expensive and costs are not always covered by health insurance. Continued research is needed on long-term SCS in PDPN to further reveal the working mechanism of the different SCS modalities, to identify predictive factors for treatment success and to improve overall success rate of SCS. Reduction in medication intake due to SCS is also visible in PDPN patients, which reduces health care costs and in addition has a positive effect on patients QoL due to less/no side effects of medication.

Nevertheless, the short-term treatment (12 months) is not cost-effective due to the high substantial initial investment of SCS. Continued follow-up of the implanted PDPN patients is necessary to demonstrate the long-term effect on pain and complications of SCS treatment in PDPN patients, and in addition the economic burden of PDPN. A thorough decision analytic model can provide better insight in the long-term cost-effectiveness of SCS in this patient group, including the long-term effect on pain, health care costs, life expectancy, longevity of the SCS material, and complication- and implantation rate of SCS. In addition, predictors for SCS treatment outcome may also lead to an increase of the cost effectiveness of SCS.

With the increasing number of potential PDPN patients, the implementation of SCS as possible treatment modality for PDPN should get a boost. Hopefully, the published literature and long-term follow-up studies on SCS in PDPN can contribute to a positive implementation of this treatment modality. A positive step has been taken to implement SCS for PDPN in the Dutch Pain Guidelines for the Dutch Association for Anesthesiology, section Pain medicine and the Flemish Association for Anesthesiology for Pain Medicine. Adding SCS for PDPN in the guidelines together with a long-term study on effectiveness and cost-effectiveness may improve further implementation of SCS as a therapeutic option, improve the treatment of patients with invalidating pain, and thereby reduce the subjective and economic burden of PDPN.

